

August 11, 2005

Arthur Neal
Director, Program Administration
National Organic Program
USDA-AMS-TMO-NOP
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RE: National Organic Program, Sunset Review Docket number TM-04-07

Dear Mr. Neal and National Organic Standards Board:

The Grocery Manufacturers Association (GMA)¹ appreciates this opportunity to provide comments on the above referenced public notice regarding the National Organic Program, Sunset Review, Docket number TM-04-07.

Please find our comments in the following attachment.

Sincerely,

Monica Gonzalez, M.S.

Director Scientific and Regulatory Policy

Cc: National Organic Standards Board

¹ The Grocery Manufacturers Association (GMA) is the world's largest association of food, beverage and consumer product companies. Led by a board of 42 Chief Executive Officers, GMA applies legal, scientific and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry. With U.S. sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states.

GMA supports the continued allowance of the following substance(s):

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Alginic acid	205.605(a)	Stabilizer; emulsifier, gelling agent, thickener; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1011 NOSB 4/95 International Organic Regulations: Australia, Codex, EU, Japan
Citric Acid	205.605(a)	Acidity regulator; Alternatives have not been available on a commercial scale.	 21 CFR 184.1033 International Organic Regulations: Australia, Canada, Codex, EU, Japan
Lactic Acid	205.605(a)	Acidity regulator; Alternatives have not been available on a commercial scale.	 21 CFR 184.1061 International Organic Regulations: Australia, Canada, Codex, EU, Japan
Agar	205.605(a)	Thickening agent; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 184.1115NOSB 4/95
Alginates	205.605(b)	Thickening agent; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 184.1724NOSB 4/95
Ammonium bicarbonate	205.605(b)	Leavening agent, pH buffer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 184.1135NOSB 4/95

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Ammonium carbonate	205.605(b)	Leavening agent, pH buffer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1137 NOSB 4/95 International Organic Regulations: Codex, EU, Japan
Ascorbic acid	205.605(b)	Preservative meats, produce; acidity regulator; nutrient (Vitamin C); antioxidant; Alternatives have not been available on a commercial scale.	 21 CFR 182.8013, 145.110, 145.115, 145.135, 145.170, 146.185, 146.187 NOSB 04/95 International Organic Regulations: Australia, Codex, EU, Japan
Bentonite	205.605(a)	Clarifying agent; Alternatives have not been available on a commercial scale.	 21 CFR 184.1155 NOSB 4/95 International Organic Regulations: Australia, Canada, EU, Japan
Calcium carbonate	205.605(a)	Calcium fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process. Alternatives have not been available on a commercial scale.	21 CFR 184.1191NOSB 11/95

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Calcium chloride	205.605(a)	Calcium fortification; There are alternative methods of providing calcium to crops and for postharvest handling. In some cases, calcium chloride is the most effective way to prevent disease. One example is its use on apples as a foliar spray and as a postharvest dip to protect against bitter pit. This has already been approved by the NOSB. Although there are alternatives for providing calcium to crops, in some situations, calcium chloride is the only effective material that prevents certain diseases.	 21 CFR 184.1193 NOSB 4/95 International Organic Regulations: Australia, Canada, Codex, Japan, EU, IFOAM
Calcium citrate	205.605(b)	Calcium fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process. Alternatives have not been available on a commercial scale.	 21 CFR 184.1195 NOSB 11/95 International Organic Regulations: Australia, EU
Calcium hydroxide	205.605(b)	Calcium fortification; Processing aid; Calcium hydroxide is listed as an approved synthetic nonagricultural substance allowed as an ingredient in organic processed food. No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1205 NOSB 04/95 International Organic Regulations: Codex, EU, Japan
Calcium hypochlorite	205.601(a)	Sanitizer; Antimicrobial; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 178.1010NOSB 11/95
Calcium phosphates (mono, di, tribasic)	205.605(b)	Leavening agent; calcium supplement; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 182.1217 NOSB 11/95 International Organic Regulations: Codex

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Calcium sulfate	205.605(a)	Coagulant for soymilk, helps fruits and vegetables retain firmness, dough conditioner; Substitute not available.	21 CFR 184.1230NOSB 3/01 Synthetic: NOSB 9/96
Carbon dioxide	205.605(b)	Activating agent; carbonation; No other way to produce a similar product without its use; No commercially available alternatives.	 21 CFR 165.110, 184.1240 NOSB 11/95 International Organic Regulations: Australia, Canada, Codex, EU, Japan
Carrageenan	205.605(a)	Thickening agent; No known suitable substitutes that would achieve same result.	 21 CFR 172.620, 182.7255 NOSB 4/95 International Organic Regulations: Codex
Cellulose	205.605(b)	Anticaking agent; filtering aid; There are very small amounts of bacterial-derived cellulose available but have not been used in food production; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR Part 172 Food additives permitted for direct addition to food for human consumption: 172.868, 172.870, 172.872, 172.874
Chlorine dioxide	205.601(a)	Sanitizer; Antimicrobial; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 173.300, 178.1010NOSB 11/95
Chlorine Materials	205.605(b)	Sanitizer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	40 CFR 141.72NOSB 11/95

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Colors, non- synthetic	205.605(a)	Coloring agent; Nutrient value from fruit/vegetable extract; Essential to produce food and beverage products that would be acceptable to consumers, does not have adverse nutritional impact.	 21 CFR 101.22 Spices and spice extractives Fruit/Vegetable extracts
Cornstarch (native)	205.606	Thickening agent; § 205.606 states, "Any non organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form." The organic corn starch now available is not enough to cover all commercial needs and is not economically feasible.	 Corn starches have been affirmed as GRAS for use in food contact surfaces in 21 CFR 182.70 and 182.90. Dextrins have also been affirmed as GRAS by the Food and Drug Administration. Regulations covering dextrins may be found in 21 CFR 184.1277. NOSB 11/95
Dairy cultures	205.605(a)	Fortify products with live cultures; Flavor dairy products; Manufacture of cheese; No other way to produce a similar product without its use.	• NOSB 10/95
Diatomaceous earth	205.605(a)	Clarifying agent; Sanitizer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 NOSB 4/95 International Organic Regulations: Australia, Canada, Codex, EU, Japan

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Enzymes	205.605(a)	Broad use; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR Part 184, 21 CFR Part 173 NOSB 11/00 animal derived NOSB 4/95 bacterial derived NOSB 10/99 fungal derived NOSB 10/99 plant derived International Organic Regulations: Japan, Codex, IFOAM
Ethylene	205.605(b)	Ripening agent; Alternatives have not been available on a commercial scale.	 29 CFR 1910.1047 EPA NOSB 11/95 and 11/99 International Organic Regulations: Japan
Ferrous sulfate (Iron)	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 184.1315NOSB 4/95

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Flavors, non- synthetic	205.605(a)	Flavor enhancer; Nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative; Alternatives have not been available on a commercial scale; Essential to produce food and beverage products that would be acceptable to consumers, does not have adverse nutritional impact.	 21 CFR 101.22 Definition of Natural flavor: The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in § 172.510 of this chapter. 21 CFR 182.10, 182.20, 182.40, 182.50 NOSB 10/95
Glycerides (mono & di)	205.605(b)	Emulsifier; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 184.1505NOSB 4/95
Glycerin	205.605(b)	Stabilizer; emulsifier; Widely used in the manufacture of organic/natural flavors.	21 CFR 182.1320, 169.175NOSB 11/95
Gums (water extracted- arabic, guar, locust (carob) bean)	205.606	Stabilizer, emulsifier, gelling agent, thickener; Alternatives have not been available on a commercial scale that will deliver with same results for specific products.	 21 CFR 184.1330, 184.1333, 184.1339; 184.1343; 184.1351, 184.1349 NOSB 11/95 International Organic Regulations: Australia, Canada, Codex, EU, Japan

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Hydrogen peroxide	205.605(b)	Aseptic packaging; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 178.1005 NOSB 11/95 International Organic Regulations: Canada
Lecithin- bleached	205.605(b)	Emulsifier; More beneficial ingredient than most of its alternatives in emulsifying products. § 205.606 states, "Any non organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form." The organic liquid lecithin now available is not enough to cover all commercial needs, is not economically feasible, and the quality of the organic fluid lecithin is not acceptable.	 Lecithin is considered to be GRAS under CFR 21, Part 184, Sec 184.1400 NOSB 4/95 International Organic Regulations: Australia, Canada, Codex, EU, Japan
Lecithin (unbleached)	205.606	Emulsifier; More beneficial ingredient than most of its alternatives in emulsifying products. § 205.606 states, "Any non organically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form." The organic liquid lecithin now available is not enough to cover all commercial needs, is not economically feasible, and the quality of the organic fluid lecithin is not acceptable.	 Lecithin is considered to be GRAS under CFR 21, Part 184, Sec 184.1400 NOSB 4/95 International Organic Regulations: Australia, Canada, Codex, EU, Japan
Magnesium chloride	205.605(b)	Protein coagulant;	 21 CFR 184.1426 NOSB 11/95 and 10/99 International Organic Regulations: Codex, EU, Japan

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Nitrogen(oil free)	205.605(a)	No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1540 NOSB 4/95 International Organic Regulations: Canada, Japan
Nutrient Minerals	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the product. Non-synthetic versions are not widely available commercially. These are required to be used in many products to comply with FDA regulations.	 21 CFR 104.20 NOSB 10/95 International Organic Regulations: Australia
Nutrient Vitamins	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the product. Non-synthetic versions are not widely available commercially. These are required to be used in many products to comply with FDA regulations.	 21 CFR 104.20 NOSB 10/95 International Organic Regulations: Australia
Ozone	205.605(b)	Sanitizer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 173.368, 184.1563NOSB 11/95
Pectin(low- methoxy)	205.605(b)	Thickening agent; Specific to certain products to achieve needed results. No other way to produce desired product without its use.	 21 CFR 184.1588 21 CFR Parts 145, 126, 131, 136, 171, 181, 150, 110, 140, 160, 161 NOSB 4/95 International Organic Regulations: Australia, Canada, Codex, EU, Japan

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Pectin (high- methoxy)	205.606	Thickening agent; Specific to certain products to achieve needed results. No other way to produce desired product without its use.	 21 CFR 184.1588 21 CFR Parts 145, 126, 131, 136, 171, 181, 150, 110, 140, 160, 161 NOSB 4/95 International Organic Regulations: Australia, Canada, Codex, EU, Japan
Phosphoric Acid	205.605(b)	Sanitizer; Compatible with sustainable agriculture and there are no clear alternatives with less compromise of organic integrity.	 21 CFR 182.1073 NOSB 10/99 USDA dairy division list of cleaning aides for dairies
Potassium citrate	205.605(b)	Emulsifier; Alternatives will not deliver product with same quality.	 21 CFR 184.1625 NOSB 4/95 International Organic Regulations: Australia
Potassium hydroxide	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1631 NOSB 11/95 International Organic Regulations: Codex, Japan
Potassium phosphate	205.605(b)	Fortification; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 184.1643NOSB 4/95
Potassium acid tartrate	205.605(b)	Leavening agent, pH buffer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1077 NOSB 11/95 International Organic Regulations: Australia, Codex, EU

Name of Substance	Location on National List	Reason for Continued Allowance/ Common use	Supporting Documents in addition to original TAP reports
Silicon dioxide	205.605(b)	Anticaking agent; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 172.480 NOSB 9/96 International Organic Regulations: Codex, EU, Japan
Sodium bicarbonate	205.605(a)	Leavening agent, pH buffer; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1736 NOSB 4/95 International Organic Regulations: Australia, Codex
Sodium citrate	205.605(b)	Emulsifier; Alternatives will not deliver product with same quality.	 21 CFR 184.1751 NOSB 4/95 International Organic Regulations: Australia, Codex
Sodium hydroxide	205.605(b)	Sanitizer; pH adjuster; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 178.1010, 184.1763 NOSB 4/95 International Organic Regulations: Australia, Codex, EU, Japan
Sodium hypochlorite	205.601(a)	Sanitizer; Antimicrobial; No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	21 CFR 178.1010NOSB 11/95
Sodium phosphates	205.605(b)	Emulsifier; pH buffer, stabilizer; Essential to produce food and beverage products that would be acceptable to consumers, does not have adverse nutritional impact; There are no non synthetic sources available.	Considered to be GRAS as multiple purpose ingredients under CFR 21, Part 182, Sec 182.1778. International Organic Regulations: Australia, Canada, Codex, EU, Japan NOSB 11/95

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Sulfur dioxide	205.605(b)	Inhibit growth of mold and bacteria; Necessary for organic wine production.	21 CFR 182.3862NOSB 4/95
Tartaric acid	205.605(a), 205.605(b)	pH adjuster	21 CFR 184.1099NOSB 11/95
Tetra sodium pyrophosphate	Approved in 2004	Emulsifier; pH buffer, stabilizer.	 21 CFR 182.6789 EPA innert ingredient list NOSB 2004 (need to add to list)
Tocopherols	205.605(b)	Antioxidant; Fortification; Alternatives not enough to cover all commercial needs and not economically feasible.	21 CFR 182.3890NOSB 11/95
Xanthan gum	205.605(b)	Thickening agent; Alternatives have not been available on a commercial scale that will deliver product with same quality.	 21 CFR 172.695 NOSB 4/95 International Organic Regulations: Canada, Australia, Codex, EU
Yeast	205.605(a)	Vitamin B source, production of bread and bread products. No other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.	 21 CFR 184.1983, 172.325, 172.590, 172.896, 172.898 NOSB 11/95 International Organic Regulations: Canada